

REMARKS

The present communication responds to the Office Action dated March 15, 2007. In that Office Action, the Examiner rejected Claims 1 and 36 under 35 U.S.C. § 102(b). The Examiner further rejected Claims 1, 22, and 23 under 35 U.S.C. § 102(e). Also, the Examiner rejected Claim 40 under 35 U.S.C. § 103(a). In response, Applicants have amended Claims 1, 22, 36, and 40. In view of the amendments and the following remarks, Applicants respectfully request reconsideration and allowance of the pending claims.

Applicants have also herewith resubmitted a copy of the Information Disclosure Statement filed June 28, 2004 and a copy of all foreign documents listed therein in accordance with the Examiner's indication that the references have not been considered. Applicants respectfully request consideration of the references.

Claim Objection

The drawings were objected to as failing to comply with 37 C.F.R. 1.84(p)(5) because they do not include reference number 734 mentioned in the description. Applicants have amended paragraph [0060] of the specification to correct a typographical error, in which "734" should read --724--. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection.

Rejections under 35 U.S.C. § 102

Rejections over Hochschuler

Claims 1 and 36 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hochschuler (US 6,099,527). Applicants respectfully traverse the rejection for at least the following reasons.

Claim 1, as amended, is directed to a fastener for stabilizing multiple bone fragments. The fastener comprises, in part, a "first portion having a curved cylindrical body" and a "second portion having a curved cylindrical body," "wherein the cylindrical body of the second portion is slidably disposed within and extending through the cylindrical body of the first portion". Claim

36, as amended, is directed to a method for operating a bone fastener used for stabilizing bone fragments, “wherein each of the first and second portions have a curved cylindrical body and wherein the cylindrical body of the second portion is slidingly disposed within and extending through the cylindrical body of the first portion”

In contrast to the claimed fastener and method of operating a bone fastener, Hochschuler discloses a bone protector that includes a two-piece eyelet, wherein the two pieces fit together through a bore in a bone. *Hochschuler, Col. 22, l. 12-Col. 23, l. 36*. Hochschuler nowhere discloses, teaches, or suggests two portions having curved cylindrical bodies.

Thus, Applicants respectfully submit that claims 1 and 36 are patentable over Hochschuler. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections of Siekierski

Claims 1, 22, and 23 were rejected under 35 U.S.C. § 102(e) as being anticipated by Siekierski (US 6,470,709). Applicants respectfully traverse the rejection for at least the following reasons.

As previously stated, Claim 1 is directed to a fastener for stabilizing multiple bone fragments. The fastener comprises, in part, a “first portion having a curved cylindrical body” and a “second portion having a curved cylindrical body,” “wherein the cylindrical body of the second portion is slidingly disposed within and extending through the cylindrical body of the first portion”.

Siekierski does not disclose, teach, or suggest a bone fastener a “first portion having a curved cylindrical body” and a “second portion having a curved cylindrical body,” “wherein the cylindrical body of the second portion is slidingly disposed within and extending through the cylindrical body of the first portion”. Rather, Siekierski discloses a threadless jewelry connector. *Siekierski, Abstract*. The connector comprises a bent elastic stem that is inserted into a hollow tube and creates an elastic, releasable friction bond, thereby holding the stem and tube together. *Siekierski, Abstract*. Figure 15, which was discussed by the Examiner, illustrates a circular piece of jewelry (e.g., earring, body piercing, etc.) employing the invention of Siekierski. At best,

Siekierski illustrates a curved piece of jewelry 164. However, Siekierski does not disclose, teach, or suggest a bone fastener. Particularly, Siekierski does not disclose, teach, or suggest a bone fastener having first and second portions, “the first portion having a curved cylindrical body” and “the second portion having a curved cylindrical body,” “wherein the cylindrical body of the second portion is slidably disposed within and extending through the cylindrical body of the first portion”. In fact, Siekierski teaches away from two curved portions as they would fail to create the friction bond envisioned by Siekierski. See *Siekierski*, Col. 9, ll. 24-28 (*describing sideways high contact force locations 180, 182, and 184*). “[T]he bending of the stem piece 170 as it is inserted due to the curvature of the internal passage creates a binding/retaining force to hold the end piece and its ball 168 in position.” *Siekierski*, Col. 9, ll. 34-37. Two curved portions would fail to create the necessary sideways high contact force locations.

Thus, Applicants respectfully submit that claim 1 is patentable over Siekierski. Claims 22 and 23, which depend from claim 1, are also patentable for at least the same reasons. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 103

Claim 40 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Vagley (US 6,158,437) and Hochschuler et al (US 6,099,527), Benderev et al. (US 6, 200,330), Lalonde (US 6,315,780) and Brinson (US 5,797,919). Applicants respectfully traverse the rejection for at least the following reasons.

Claim 40 is directed to an instrumentation kit for use in stabilizing bone fragments. The instrumentation kit comprises, in part, “a first plurality of bone fasteners, each being configured to extend through the bone fragments and including a first and second portions shaped and dimensioned to initially engage and further move relative to each other to a locked position . . . a second plurality of bone fasteners, each being configured to have a pair of jaws pivotal relative to one another about joined proximal ends thereof to a locked position . . . a third plurality of fasteners each made from a memory shape alloy and having at least one of opposite ends formed with a plurality of deformable webs, whereas, as the bone fastener of the third plurality moves through the bone fragments to the locked position, the deformable fingers are peeled away to

engage a facet of at least one of the bone segments in response to heat applied to the fasteners . . . and a fourth plurality of bone fasteners, each being configured to have a respective pair of jaws linearly displaceable relative to one another to a locked position.”

None of the references, i.e., Vagley, Hochschuler, Benderev, Lalonde, and Brinson, alone or in combination, teach or suggest all the elements recited in Applicants’ Claim 40. For example, none of the references teach or suggest bone fasteners “configured to have a pair of jaws pivotal relative to one another about joined proximal ends thereof to a locked position” nor bone fasteners “made from a memory shape alloy and having at least one of opposite ends formed with a plurality of deformable webs, whereas, as the bone fastener of the third plurality moves through the bone fragments to the locked position, the deformable fingers are peeled away to engage a facet of at least one of the bone segments in response to heat applied to the fasteners.”

The Examiner points to Brinson for teaching a bone clamp, wherein a pair of jaws are pivotal relative to each other and can be locked using a locking mechanism. Applicants respectfully assert, that Brinson does not teach or suggest a bone fastener “configured to have a pair of jaws pivotal relative to one another about joined proximal ends thereof.” Rather, Brinson discloses a scissors-like clamp device secured at a pivot point generally in the center of the device. *See Brinson, Col. 3, ll. 53-59; Figs. 1, 2, and 5.*

The Examiner further points to Benderev for teaching a bone fastener manufactured from a shape memory material wherein at least one end has deformable webs that separate and engage an inner surface of the bone. Applicants respectfully assert that Benderev does not teach or suggest a bone fastener “made from a memory shape alloy and having at least one of opposite ends formed with a plurality of deformable webs, whereas, as the bone fastener . . . moves through the bone fragments to the locked position, the deformable fingers are peeled away to engage a facet of at least one of the bone segments in response to heat applied to the fasteners.” Rather, Benderev discloses a surgical implant, or bone hook, having opposed flanges which flare out when introduced into the bone. *See Benderev, Col. 8, l. 66-Col. 9, l. 23.* The flanges are designed to spread apart and become more deeply embedded within the bone to the extent pressure is applied in the direction indicated by the letter “D” in Figure 7 of Benderev. *See*

Benderev, Col. 9, ll. 10-15. That is, pressure is necessary to make the flanges of the bone hook flare out into the bone. Furthermore, the implant in Benderev embeds in an inner surface of the bone. The surgical implant of Figure 7 in Benderev is not made of memory shape alloy, does not comprise deformable fingers that are peeled away to engage a facet, and does not comprise fingers that deform when heat is applied.

Furthermore, Applicants respectfully assert that Vagley, Hochschuler, Benderev, Lalonde, and Brinson are not combinable references. The Examiner asserts that Vagley discloses a surgical procedure employing a surgical kit. Applicants respectfully assert that the references cannot be combined merely because Vagley discloses a surgical kit. Vagley discloses a kit comprising surgical instruments, such as those for rhinoplasty, presented generally in the sequence they will be used during the surgical procedure and further having a graphic representation, textual indication, or instrument recess, to facilitate identification of the surgical instrument for purposes of proper delivery of the instrument to the doctor performing the surgery. See *Vagley, Col. 5, ll. 24-34*. Nowhere does Vagley disclose an instrumentation kit for use in stabilizing bone fragments, particularly the instrumentation kit recited in Applicants' Claim 40.

Thus, Applicants respectfully submit that claim 40 is not made obvious over Vagley, Hochschuler, Benderev, Lalonde, and Brinson. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

This application now stands in allowable form and reconsideration and allowance are respectfully requested.

No additional claim fees should be generated by this paper. However, the Commissioner is hereby authorized to charge any fee deficiency associated with this paper to Deposit Account No. 04-1420.

Respectfully submitted,

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